K032200
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EXHIBIT 2

510(k) Summary

REMCO ITALIA S.p.A.
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Contact: Carlo Depero, Director
Date: July 1, 2003

OCT 0 3 2003

1. Identification of the Device:
   Proprietary-Trade Name: **ELAN® Digital 12 Channel Electrocardiograph.**
   Classification Name: 74 DPS and LOS
   Common/Usual Name: Electrocardiograph, ECG Analysis

2. Equivalent legally marketed devices The legally marketed device to which equivalence is being claimed is the M1770A Pagewriter 200i manufactured by Hewlett-Packard, K954980, Brentwood "Telemed 12 Lead Resting ECG Analysis Library," K010505 and Telemed Omnigraph 6000, K880357

3. Indications for Use (intended use) ELAN® is a digital 12 channel electrocardiograph designed for acquisition and digitization of conventional diagnostic 12-lead simultaneous ECG waveforms and ECG data and real-time visualization of 1 to 6 leads on its built-in LCD monitor. ELAN® can also record and store in its internal memory up to 100 ECG tests. Each ECG test can be analyzed, printed on the internal thermal printer and/or sent to a PC via serial cable, LAN or modem. ELAN® can perform automatic measurements of ECG waveform and preliminary interpretation of ECG test; measurements and diagnostic statements are offered to the physician on an advisory basis only; the physician is asked to review and validate or change the ECG interpretation.

4. Description of the Device: ELAN® is a digital 12 channel electrocardiograph for the simultaneous acquisition of the 12 ECG leads, featuring 6-lead LCD screen, alphanumeric keyboard and high resolution thermal printer on 210 mm paper. ELAN ® can record and store in its internal memory up to 100 ECG tests. Each ECG test can include patient data, ECG measurements, automatic interpretation, physician report. Stored ECG tests can be reviewed, printed on the internal thermal printer and/or sent to a local or remote PC via serial cable, LAN network or external standard modem.

5. Safety and Effectiveness, comparison to predicate device. The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

SPECIFICATION	PAGEWRITER 200i, K954980	ELAN
CONFIGURATION	Tabletop / cart mount (optional)	Tabletop
LEADS		
Lead switching	Automatic / manual	Automatic / manual
Sensitivity, mm/mV	5, 10, 20	5, 10, 20
Calibration signal	Manual	Manual
Frequency range, Hz Diagnostic	0.05 - 150	0.05 - 150
Filtered	Notch, EMG, baseline wander	Notch, EMG, baseline wander
Input impedance, Mohms	100	160 Mohms at 10 Hz
CMRR @ 60 Hz, dB	110	> 100
Leads-off indicator	Yes	Yes
RECORDER		
Recording method	Digital thermal array	Digital thermal array
Paper size	A4	210 mm z-fold
Lead marker	Automatic	Automatic
Timing marker	No	No
Event marker	No	No
Chart speed, mm/sec	5, 10, 25, 50	6.25, 12.5, 25, 50
Channels acquired simultaneously	12	12
Channels printed simultaneously	3,6,12	3, 6, 12
PREVIEW SCREEN	LCD	LCD
NO. WAVEFORMS STORED	Optional 30, flash	Flash 25, optional 100
ECG TRANSMISSION	Optional	Yes
Type	Fax, Programmable modem, RS232	Programmable modem, RS232, LAN
INTERPRETATION	Yes	Yes
ECG MEASUREMENTS	Yes	Yes
DEFIBRILLATOR OVERLOAD PROTECTION	Yes	Yes
POWER REQUIREMENTS	110-220 VAC	115-230 VAC
DIMENSION, mm	102x432x381	340 x 400 x 110
WEIGHT, Kg	8.5	5.8
BATTERY OPERATION	Yes	Yes
Battery type	Lead acid	Built-in rechargeable NiMH
No. / Voltage	1/6	20 / 1.2 V
Operating time, hours	40 min	5 patient monitoring 2 printing
ENVIRONMENTAL		
Operating temperature	+10 to +40 °C	+10 to +40 °C
Operating humidity (non condensing)	25% to 75%	25% to 75%
Operating altitude	700-1060 mbar	700-1060 mbar
PLANNING & PURCHASE		
Warranty	3 years in USA	2 years in USA

7. Conclusion

After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of Remco Italia S.p.A. that the ELAN® Digital 12 Channel Electrocardiograph is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 3 2003

REMCO ITALIA S.p.A.
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K032200
Trade Name: ELAN® Digital 12 Channel Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph, ECG Analysis
Regulatory Class: Class II (two)
Product Code: DPS
Dated: September 15, 2003
Received: September 16, 2003

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K032200

Device Name: ELAN® Digital 12 Channel Electrocardiograph.

Indications for Use:

ELAN® is a digital 12 channel electrocardiograph designed for acquisition and digitization of conventional diagnostic 12-lead simultaneous ECG waveforms and ECG data and real-time visualization of 1 to 6 leads on its built-in LCD monitor.

ELAN® can also record and store in its internal memory up to 100 ECG tests. Each ECG test can be analyzed, printed on the internal thermal printer and/or sent to a PC via serial cable, LAN or modem.

ELAN® can perform automatic measurements of ECG waveform and preliminary interpretation of ECG test; measurements and diagnostic statements are offered to the physician on an advisory basis only; the physician is asked to review and validate or change the ECG interpretation.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K032200

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)